

REMARKS

Reconsideration of this application, as amended, is respectfully requested. Claim 1 has been amended and claim 18 has been cancelled. These amendments do not add any new matter and find support in the originally filed application. Applicants reserve the right to reincorporate any cancelled or otherwise presently unclaimed subject matter in this application as appropriate or to prosecute the same in subsequently filed applications. Consideration and entry of this amendment is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 16-22 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Claim 16, part (d) has been deleted from claim 1. Claim 18 has been cancelled. The rejections are therefore moot as to claim 16, part (d) and claim 18.

Claim 16, part (c), stands rejected as vague and indefinite. As shown in Figure 8B, SEQ ID NOS. 60 and 18 are sense and antisense primers, respectively, for amplifying the strain 33 hia gene from the V38 codon to the SnaBI site. This sequence corresponds to nucleotides 131-379 illustrated in Figures 18A-B. Applicants respectfully maintain that the meaning of claim 16, part (c), is not vague and / or indefinite and request that this rejection be withdrawn.

Claim 16, part (e) (amended to part (d) and referred to as such below), stands rejected as vague and indefinite. Claim 16, part (e) refers to the “V38 N-truncated *Haemophilus influenzae* adhesion (Hia) protein of non-typeable strain 33 of *Haemophilus influenza*” which is described at Example 7 of the instant application. Read in view of the specification, the meaning of the disputed phrase would be clear to one of skill in the art. Applicants respectfully maintain that the meaning of claim 16, part (d), is not vague and / or indefinite and request that this rejection be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 16-22 stand rejected under 35 U.S.C. § 112, first paragraph as not being enabling for the subject matter of parts (c), (d), and (e) of claim 16. Parts (c), (d) and (e) of claim 16 have been cancelled; the rejection as to those parts of claim 16 is therefore moot.

The Examiner stated at p. 5 of the Office Action that the specification is enabling for the subject matter of parts (a) and (b) of claim 16. However, at p. 5, the Examiner states that “the instant specification fails to demonstrate that any of the polypeptides recited in parts (a)-(e) of claim 16 meet any of the three considerations known in the art to be important” in producing vaccines. Applicants respectfully disagree.

As shown in Example 11, even a single administration of the V38 rHia (33) protein to mice resulted in a “significant anti-V38 rHia antibody response[s]”. And Example 13 demonstrates that administration of the same protein in a chinchilla model of nasopharyngeal colonization resulted in partial protection from challenge by the NTII strain 33. Thus, the V38 rHia (33) was shown to be immunogenic and provide protection in an accepted animal model of vaccination against *H. influenzae*. Claim 16 relates to immunogenic compositions “comprising a recombinant *Haemophilus influenzae* adhesion (Hia) protein of non-typeable strain 33 of *Haemophilus influenzae*”, the immunogenicity of which is exemplified by at least Example 11. Claim 17 relates to an “immunogenic composition of claim 16 formulated as a vaccine for in vivo administration to protect against disease caused by *Haemophilus*” which is exemplified by at least Example 13. The immunogenicity of V38 rHia (33) is merely exemplary of that one of skill in the art would expect from the other claimed rHia species. Applicants respectfully maintain that one of skill in the art would be enabled by the specification to produce and utilize the claimed compositions as vaccines, as instantly claimed.

Applicants respectfully maintain that the above discussion clearly demonstrates that the pending claims are enabled by the instant specification as required by 35 U.S.C. § 112, first paragraph. As such, it is respectfully requested that these rejections be withdrawn.

CONCLUSIONS

Applicants believe the claims are in condition for allowance and respectfully request that a Notice of Allowance be issued as soon as possible. The Examiner is encouraged to contact the undersigned with any comments and / or questions.

Respectfully submitted,

Date: April 6, 2009

Patrick J. Halloran

Patrick J. Halloran

Reg. No. 41,053

Patrick J. Halloran, Ph.D., J.D.
3141 Muirfield Road
Center Valley, PA 18034
Tel: 610-984-4751
Fax: 484-214-0164
e-mail: pat@pathalloran.com